

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

AMENDMENT 1  
AMENDEMENT 1

**Medical electrical equipment –  
Part 2-35: Particular requirements for the basic safety and essential performance  
of heating devices using blankets, pads or mattresses and intended for heating  
in medical use**

**Appareils électromédicaux –  
Partie 2-35 : Exigences particulières pour la sécurité de base et les  
performances essentielles des dispositifs de réchauffage utilisant des  
couvertures, des coussins ou des matelas et destinés au réchauffage des  
patients en usage médical**





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IEC Secretariat  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Amendment 1 to IEC 60601-2-35:2020 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this Amendment is based on the following documents:

Draft	Report on voting
62D/2088/FDIS	62D/2108/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications/](http://www.iec.ch/publications/).

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[IEC 60601-2-35:2020/AMD1:2023](https://standards.iteh.ai/catalog/standards/iec/6fb4577c-ebdb-4d12-a80d-b6965d9ebc65/iec-60601-2-35-2020-amd1-2023)

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## INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1815/RR.

## 201.1 Scope, object and related standards

Replace the existing footnote 1 with the following new footnote:

The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

### 201.1.3 Collateral standards

Replace the existing second paragraph with the following new paragraph:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply as modified in Articles 202, 208 and 210 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

### 201.1.4 Particular standards

Replace, in the existing third paragraph, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" with "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

## 201.2 Normative references

Replace the existing references to IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-10 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-10:2007/AMD1:2013

IEC 60601-1-10:2007/AMD2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-2:2014/AMD1:2020

## 201.3 Terms and definitions

Replace, in the existing first paragraph, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" with "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

### 201.7.2.1.101.2 CONTROLLERS

Replace the two existing paragraphs of item a) with the following new item:

- a) The HOSE shall be marked within 15 cm of the NOZZLE to caution that the NOZZLE needs to be connected to a BLANKET. The safety sign ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, safety sign 10) shall accompany the "NO FREE HOSING" safety sign shown in Annex D of this particular standard.